

Atty. Dkt. No. 078883-0145

RECEIVED

JAN 1 7 2003

TECH CENTER 1600/2900

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Philippa RADCLIFFE et al.

Title:

TRANSGENIC ORGANISM

Appl. No.:

10/082,122

Filing Date:

02/26/2002

Examiner:

Unassigned

Art Unit:

1632

## UNDER 37 CFR § 1.56

Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

Atty. Dkt. No. 078883-0145



Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding United Kingdom application. A copy of the United Kingdom Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

**FOLEY & LARDNER** 

Customer Number: 22428

Date in 16 Dec 3

Facsimile:

Telephone: (202) 672-5538 (202) 672-5399

Michele M. Simkin Attorney for Applicants

Registration No. 34,717

PTO/SB/08 (08-00)

Appro ed for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OHB corporation

Sheet

| Substitute for form 1449B/PTO     |                        | Complete if Known     | 7            |
|-----------------------------------|------------------------|-----------------------|--------------|
| INFORMATION DISCLOSURE            | Application Number     | 10/082,122            | IAN 1 6 7003 |
| STATEMENT BY APPLICANT            | Filing Date            | 02/26/2002            | JAN          |
| Date Submitted: 01/16/2003        | First Named Inventor   | Philippa RADCLIFFE et | 5            |
|                                   | Group Art Unit         | 1632                  | TAN TART     |
| (use as many sheets as necessary) | Examiner Name          | Unassigned            | 3 TANDEMA    |
| 1 of 1                            | Attorney Docket Number | 078883-0145           |              |

|                       |              |                 |                               | U.S.     | PATENT DO                        | CUMENTS |  |  |
|-----------------------|--------------|-----------------|-------------------------------|----------|----------------------------------|---------|--|--|
| Examiner<br>Initials* | Cite<br>No.1 | U.S. Patent Doo | Kind<br>Code <sup>2</sup> (if | · Name o | of Patentee or A<br>Cited Docume |         | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                       |              | •               | known)                        | . *      |                                  |         | - 0  | · · · · · · · · · · · · · /  |
|                       |              |                 |                               |          |                                  |         | 3 0-   | • •  |
| -                     |              |                 | 1-                            |          | 1                                | -       |  |  |
| -                     |              | •               |                               | •        |                                  |         |  | - *  |

|                    |              |                           |                                       | FC   | DREIGN PATENT DOCUMEN                               | TS   |  |                |
|--------------------|--------------|---------------------------|---------------------------------------|--|---|--|--|----------------|
| Examiner Initials* | Cite<br>No.1 | Fo<br>Office <sup>3</sup> | reign Patent (<br>Number <sup>4</sup> | Document<br>Kind Code <sup>5</sup><br>(if known) | Name of Patentee or<br>Applicant of Cited Documents | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|                    | A1           | wo .                      | 01/44458                              | A2   | NOVARTIS AG   | 06/21/2001   | 11)  |                |
|                    | A2           | WO .                      | 00/73482                              | A1   | CHIRON CORP. ET AL.                                 | 12/07/2000   |  |                |
|                    | A3           | wo .                      | 98/51810                              | A1   | UNI. NORTH CAROLINA                                 | 11/19/1998   | RECEIV   | EL             |
|                    |              |                           |                                       |  |   |  | JAN 1-7-2  | 003            |
|                    |              | - •                       |                                       |  | · · · · · · · · · · · · · · · · · · ·               |  |  | 1000           |
|                    |              | •                         |                                       |  |   |  | TECH CENTER  | PUU            |

|              | OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS  |   |
|--------------|--|---|
| Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | Т <sup>6</sup>  |
| A4           | TARANTAL ET AL., "Lentiviral Vector Gene Transfer into Fetal Rhesus Monkeys ( <i>Macaca mulatta</i> ) <i>Mol. Ther.</i> (2001) , Vol. 4, No. 6, pp. 614-621.   |   |
| A5           | WOLFGANG ET AL., "Rhesus monkey placental transgene expression after lentiviral gene transfer into preimplantation embryos," <i>Proc. Natl. Acad. Sci. USA</i> (2001), Vol. 98, No. 19, pp. 10728-10732.   |   |
| A6           | STEIN ET AL., "In Vivo Treatment of Hemophilia A and Mucopolysaccharidosis Type VII Using Nonprimate Lentiviral Vectors," Mol. Ther. (2001), Vol. 3, pp. 850-856.  | •   |
| A7           | BERKOWITZ ET AL., "Construction and Molecular Analysis of Gene Transfer Systems Derived from Bovine Immunodeficiency Virus," <i>J. Virol.</i> (2001), Vol. 75, No. 7, pp. 3371-3382.   |   |
| A8           | TARANTAL ET AL., "Rhesus Monkey Model for Fetal Gene Transfer: Studies with Retroviral-Based Vector Systems," <i>Mol. Ther.</i> (2001), Vol. 3, No. 2, pp. 128-138.  |   |
|              | A4 A5 A6 A7  | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.  A4 TARANTAL ET AL., "Lentiviral Vector Gene Transfer into Fetal Rhesus Monkeys ( <i>Macaca mulatta</i> ) <i>Mol. Ther.</i> (2001), Vol. 4, No. 6, pp. 614-621.  A5 WOLFGANG ET AL., "Rhesus monkey placental transgene expression after lentiviral gene transfer into preimplantation embryos," <i>Proc. Natl. Acad. Sci. USA</i> (2001), Vol. 98, No. 19, pp. 10728-10732.  A6 STEIN ET AL., " <i>In Vivo</i> Treatment of Hemophilia A and Mucopolysaccharidosis Type VII Using Nonprimate Lentiviral Vectors," <i>Mol. Ther.</i> (2001), Vol. 3, pp. 850-856.  A7 BERKOWITZ ET AL., "Construction and Molecular Analysis of Gene Transfer Systems Derived from Bovine Immunodeficiency Virus," <i>J. Virol.</i> (2001), Vol. 75, No. 7, pp. 3371-3382.  A8 TARANTAL ET AL., "Rhesus Monkey Model for Fetal Gene Transfer: Studies with Retroviral-Based Vector |

| Examiner  | Date       |
|-----------|------------|
| Signature | Considered |
|           |            |

\*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

Unique citation designation number. See attached Kinds of U.S. Patent Documents. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached

Burden Hour Statement This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patents, Washington, D.C. 20231.